Senate Bill 677

Barrier Protection:

Although the goal of protecting latex sensitive individuals is laudable, it does so with the unintended consequence of compromising the unmatched barrier protection offered by latex gloves.

OSHA Bulletin:

The S.1106 legislative findings cite the attached 2008 OSHA bulletin recommending strategies for risk reduction. It is important to note that this bulletin actually recommends the use of low-protein powder-free gloves, rather than the phasing out of latex gloves entirely.

Current FDA Recommendation:

The FDA's current recommendation regarding latex gloves is not a complete phase out but, rather, the use of non-powdered low-protein latex gloves (please see below). Therefore, we respectfully request that you consider amending S.1106 to prohibit only *high* powder-*high* protein latex gloves, rather than all latex gloves.

In 2016, the FDA banned *powdered* surgeon gloves, *powdered* patient examination gloves. However, they **did not** recommend a complete ban of latex gloves. Below please find an FDA public comment exchange regarding non-powdered latex gloves:

FDA—Docket No. FDA-2015-N-5017, RIN 0910-AH02

"In our 2008 Medical Glove Guidance Manual (Ref. 1), we recommend that non-powdered gloves have no more than 2 milligrams (mg) of residual powder and debris per glove, as determined by the Association for Testing and Materials (ASTM) D6124 test method (Ref. 2). The Agency continues to believe this amount is an appropriate maximum level of residual powder."

FDA Public Comment Summary: Several comments identify risks that result from the use of powdered and non-powdered NRL gloves. These comments request FDA to extend the ban to all NRL gloves, both powdered and non-powdered.

FDA Response: Unlike with powdered latex gloves, which have the ability to aerosolize glove powder and carry allergenic proteins, FDA believes the risk of allergic reaction to non-powdered NRL gloves, which affects the user and patients in direct contact with the glove, is adequately mitigated through already-required labeling that alerts users to this risk. NRL gloves must include a statement to alert users to the risk of allergic reactions caused by NRL (21 CFR 801.437). Further, several studies have indicated that the use of non-powdered NRL gloves reduces the risk of sensitization to allergenic NRL proteins and the number of allergic reactions experienced by those who are already sensitized (Refs. 18, 19, and 20). FDA believes that these study results, when considered alongside the risk mitigation that follows from FDA's required labeling for NRL products, demonstrates that non-powdered latex gloves can be safely used with appropriate caution for latex-sensitive patients and health care workers. Therefore, the FDA has determined not to ban the use of all NRL gloves.

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Additional Findings: Allergies in the Food Industry & Food Ingestion

There are no reported deaths caused by latex protein allergy through food ingestion. Milk, peanuts, and fish, kill ~150 allergic people annually in the U.S. (*Fatalities due to anaphylactic reactions to foods*, J. Allergy and Clinical Immunology, 2001; 107:191-193).

A 2000 study showed when food preparers used low protein-powder free gloves **no protein transfer was detected** (Beezhold et. al. Allergy Asthma Proc. 2000 Sep-Oct., 2(5), 301-6).

April 2002 Conference on Food Protection (CFP): FDA reported that although the 75 self-reported cases of food-mediated latex allergies were received from consumers in late 2000 and early 2001, these cases "***are not clinically verified through medical records and it is possible that some of the reactions described could have been due to consumption of foods that cross react to latex protein*** (e.g. kiwi, bananas, buckwheat, stone fruits, potatoes, tomatoes, sweet pepper, chestnuts, spinach, etc.)" CFP concluded that there was much uncertainty about allergens being transmitted from latex gloves and their effects on consumers, and there was a need for more studies on this matter.

> *Note: Cross-reactivity occurs when your body's immune system identifies the proteins in one substance (e.g. latex protein) and the proteins in another (e.g. fruit & vegetables) as being similar. When you come into contact with either, whether it is in the presence of the protein that you are truly allergic to or not, your immune system can react in the same way, which can then cause your allergic symptoms (*Latex Allergy – Latex Cross-reactive foods. Fact Sheet. American Latex Allergy Association, 8-09; Latex-Food Cross-Reactivity, Latex Allergy Resources).

"The evidence is suggestive of a **weak positive relationship** between the use of natural rubber latex gloves and food-mediated latex allergic reactions. The data linking the presence of these [latex] proteins in foods to allergic reactions is **based primarily on anecdotal evidence**, and is **very weak**." August 2003, the Additives and Ingredient Subcommittee of the Food Advisory Committee to the FDA's Center for Food Safety and Applied Nutrition (*Executive summary of the meeting of the Additives and Ingredients Subcommittee of the Food Advisory Committee, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Aug. 26-27, 2003, Washington, D.C.).*

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